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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,066	03/27/2001	Shuping Tong	00786-287004 / MGH-0960.3	1622
26161	7590	02/10/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,066

Applicant(s)

TONG ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-14-2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17. 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on October 14, 2003 has been entered.

2. Currently, claims 1-9 are pending and under consideration in the present application.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on October 14, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khudyakov et al., J Virol 68: 7067-74 in view of the combined teachings of Chassot et al., Virology 200: 72-78

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and Yuasa et al., Virology 181: 14-21. These claims read on polypeptides comprising a first part identical to residues 1-102, or fragments thereof comprising at least residues 80-102, of a hepadnavirus pre-S protein, and a second part comprising a sequence not identical to any part of the pre-S protein, and which may be glutathione S-transferase (GST). The claim is to be interpreted such that the "identical to" language is read as equivalent to the closed "consisting of" language described in MPEP § 2111.03. Khudyakov teaches the making and use of a chimeric protein comprising epitopes of a hepadnavirus and either GST or β -galactosidase. The reference teaches that mosaic proteins have a useful role in the immunodiagnostic and immunotherapeutic arts. Pages 7072-73. However, while the reference suggests the use of such a chimeric protein generally, the reference does not suggest the making and use of such a protein comprising residues 80-102 or 1-104 of a hepadnavirus pre-S protein.

Yuasa discloses the duck hepatitis B virus (DHBV) pre-S protein of SEQ ID NO: 34. See, Fig. 6, page 19, residues 37-197. This reference teaches that neutralizing epitopes of the protein may be found at residues 91-99 of the protein (numbering correct to account for the removal of the 36 residues in front of the predicted start of the protein in the figure). Further, Chassot teaches an additional neutralizing epitope in residues 83-90 of the pre-S protein. Page 75. Thus, it would have been obvious to those in the art to make a chimeric polypeptide as described in Khudyakov comprising these two epitopes. It is noted that the Chassot and Yuasa references teach other antigenic regions in addition to these. However, as these epitopes are disclosed as reactive with neutralizing antibodies, it would have been obvious to those in the art to use a polypeptide as described in Khudyakov comprising these epitopes to detect neutralizing DHBV antibodies in a sample. As the presently claimed polypeptides are obvious variants of the

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epitopic regions comprising these epitopes, the teachings of these references renders the claimed invention obvious. Those in the art would have had a reasonable expectation that the combination of these references to create the claimed polypeptide would result in a polypeptide effective for the identification of DHBV neutralizing antibodies.

Applicant's disclosure regarding the binding capacities of the claimed peptides with respect to the p170 and p120 proteins is noted. However, as these regions appear to overlap with the antigenic regions indicated by the references above, these teachings are not found to provide sufficient evidence of the novelty or non-obviousness of the claimed regions to distinguish over the prior art.

6. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khudyakov et al., J Virol 68: 7067-74 in view of the combined teachings of Chassot et al., Virology 200: 72-78 and Yuasa et al., Virology 181: 14-21. These claims read on subject matter similar to that of claim 1-5, except that the minimum region of the hepadnavirus pre-S protein sequence comprises residues 98-161. The teachings of Khudyakov have been described above, as have the teachings, in part, of the Chassot and Yuasa references. Chassot and Yuasa additionally teach other neutralizing epitopes of the DHBV pre-S protein, found at residues 100-107 (Chassot, page 75) and at residues 139-145 (Yuasa, Fig. 6, correcting for the 36 residue difference). The references also identify other antigenic, though not necessarily neutralizing, regions within this range. Thus, it would have been obvious to those in the art to make chimeric polypeptides according to Khudyakov comprising the indicated region of the DHBV pre-S protein for the detection of anti-pre-S protein antibodies.

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Conclusion

7. No claims are allowed.
8. The following prior art references are made of record and are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

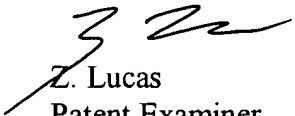
Schlicht et al., J Virol 67 :2280-85. This reference teaches the making and use for detection of anti-pre-S antibodies of a chimera of pre-S proteins and bacterial MS2 polymerase. The reference does not however teach or suggest chimeras comprising the presently claimed pre-S protein fragments.


Klinkert et al., J Virol 58 :522-25. This reference teaches a chimeric protein comprising a pre-S sequence with residues 20-120. The reference does not teach chimeric proteins comprising the specific fragments in the claimed polypeptides.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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2/9/04